

REMARKS

In the Office Action, the Examiner rejected claims 1-28. In the previous Response to the Office Action mailed March 8, 2007, the Applicants cancelled claims 14-18. Claims 1-13 and 19-28 remain pending in the present application and are believed to be in condition for allowance. In view of the following remarks, the Applicants respectfully request reconsideration and allowance of all pending claims.

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claims 1, 4-7, 19, and 22-28 under 35 U.S.C. § 103(a) as being unpatentable over McConville, (U.S. Patent No. 5,826,277, hereinafter “McConville”) over Westbrook et al., (U.S. Patent No. 6,811,538, hereinafter “Westbrook”); claims 8-13 under 35 U.S.C. § 103(a) as being unpatentable over McConville over Westbrook; and claims 2, 3, 20, and 21 under 35 U.S.C. § 103(a) as being unpatentable over McConville in view of Westbrook and further in view of German patent document 29515977, (hereinafter “German patent document”).

Legal Precedent

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). However, it is not enough to show that all the elements exist in the prior art since a claimed invention composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). It is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* Specifically, there must be some articulated reasoning with

a rational underpinning to support a conclusion of obviousness; a conclusory statement will not suffice. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Indeed, the factual inquiry determining whether to combine references must be thorough and searching, and it must be based on *objective evidence of record*. *In re Lee*, 61 U.S.P.Q.2d 1430, 1436 (Fed. Cir. 2002). One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983); M.P.E.P. § 2145. Moreover, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959); *see* M.P.E.P. § 2143.01.

Rejection of claims 1, 4-7, 19, and 22-28 as being unpatentable over McConville, over Westbrook

In rejecting claims 1, 4-7, 19, and 22-28, the Examiner stated:

McConville (5826277) teaches the invention as claimed including an elastic segment (12) sized to fit around a wearer's head; and a non-elastic segment (20) being smaller than and attached with said elastic segment, said non-elastic segment sized to span a portion of said elastic segment when said elastic segment is stretched, said non-elastic segment being larger than said portion of said elastic segments it spans when said elastic segment is not stretched. However, the head band of McConville does not teach a sensor coupled to the headband. Westbrook teaches that headbands are used for holding sensors on a wearer's head. It would have been obvious at the time the invention was made to provide the McConville headband with a sensor in order to monitor the pulse rate and oximetry as shown by Westbrook.

Office Action, p. 2.

The Examiner has asserted that McConville teaches a headband with an elastic segment 12 and a non-elastic segment 20 smaller than the elastic segment. For purposes of this discussion, the Applicants will assume that the Examiner meant to indicate sponge cloth 14, which in an unstretched state may exhibit slack 20 and which is referred to as “inelastic,” as being allegedly analogous to the non-elastic segment. See McConville, Abstract; col. 3, lines 10-34. The Examiner has further noted that McConville does not teach a sensor coupled to the headband, but that combination with Westbrook overcomes this deficiency. The Applicants respectfully disagree that the combination of McConville and Westbrook teaches all elements of independent claims.

Regarding claims 1 and 4-7, independent claim 1 is directed towards a headband including a non-elastic segment “attached to the elastic segment on an exterior side of the elastic segment.” The McConville reference does not teach a non-elastic segment attached to an elastic segment on an exterior side of the elastic segment. In particular, the Applicants note that the McConville reference discloses a sweat band with an interior sponge cloth for increased sweat absorption. See McConville, col. 2, lines 40-46; col. 3, lines 24-25. As disclosed in McConville, the sponge layer is pulled against the elastic sweat band when the band is pulled across the wearer’s head. “For example, when the sweat band is worn, the sponge cloth extends across the user’s forehead from ear to ear.” McConville, col. 3, lines 12-14. McConville includes no teaching or suggestion of providing a non-elastic segment on an exterior side of the sweat band. Because the sponge cloth as recited in the McConville reference is for the purpose of absorbing sweat produced by the forehead, it is clear that a configuration in which the sponge portion were on the exterior surface of the band would not serve the purpose of absorbing sweat. Combination with Westbrook does not overcome the deficiency of McConville because Westbrook does not appear to disclose a non-elastic segment attached to an elastic segment on an exterior side of the elastic segment.

Turning to independent claim 19, this claim is directed toward a headband including a non-elastic segment, “wherein the non-elastic segment has less slack when the elastic segment is applied to a patient’s head with sufficient tension to deliver pressure in the range higher than venous pressure and lower than capillary pressure to the wearer’s head.” The McConville and Westbrook references do not disclose or suggest a headband including a non-elastic segment that has decreased slack when the headband is applied to a patient’s head with sufficient tension to deliver pressure in the range higher than venous pressure and lower than capillary pressure to the wearer’s head. Indeed, the Examiner has provided no reference to any such teaching or suggestion in either the McConville or the Westbrook references.

Regarding independent claim 28, the McConville and Westbrook references do not disclose or suggest a headband including a non-elastic segment that is attached on an exterior side of the elastic segment in such a manner that the non-elastic segment projects out from the surface of the elastic portion when the headband is not sufficiently tight, thus creating a loop which provides a visual indication that the headband needs re-tightening. As noted above, the McConville reference discloses a sweat band with an interior sponge cloth for increased sweat absorption. The sponge layer is pulled against the elastic sweat band when the band is pulled across the wearer’s head. The McConville reference does not teach or suggest a non-elastic segment on an exterior side of the sweat band. Further, there is no teaching or suggestion in McConville that any slackness in any part of the sweat band may provide an indication of the tightness of the sweatband, and the Examiner has provided no reference to any such teaching or suggestion in either the McConville or the Westbrook references.

For at least the reasons outline above, the Applicants respectfully request withdrawal of the rejection of claims 1, 4-7, 19, and 22-28 under 35 U.S.C. § 103(a).

Rejection of claim 8-13 as being unpatentable over McConville, over Westbrook

In rejecting claims 8-13, the Examiner stated:

The combined teaching of over McConville (5826277) over Westbrook et al (US 6,811,538) set forth the invention as claimed. However, the inelastic segments of McConville are the small elements rather than the elastic segments being smaller. It would have been obvious to provide the elastic segments as smaller and the inelastic segment as sized to fit around the head since such an arrangement is merely a reversal of the parts and because such a change would work in the same manner and in order to provide a lower amount of elasticity due to the smaller amount of elastic in the headband.

Office Action, pp. 2-3.

Independent claim 8 recites an inelastic segment with an elastic segment “being smaller than and attached to the inelastic segment on an exterior side of the inelastic segment” and a “sensor coupled to the headband on a patient side of the inelastic segment opposite the exterior side.” The Examiner has asserted that McConville teaches a headband with an elastic segment and a non-elastic segment smaller than the elastic segment. The Examiner has noted that the McConville reference does not teach the particular arrangement recited in claim 8, but instead teaches the reverse configuration, namely an elastic band with non-elastic segments being smaller than elastic segments. The Examiner has further noted that McConville does not teach a sensor coupled to the headband, but that combination with Westbrook overcomes this deficiency. The Applicants respectfully disagree that the combination of McConville and Westbrook teaches all elements of independent claims. The Applicants also assert that the modification of McConville to reverse the arrangement of the part is improper, because such an arrangement would render McConville unsuitable for its intended purpose.

As noted above, claim 8 recites that the elastic segment is “on an exterior side of the inelastic segment” While the McConville reference does appear to disclose a headband segment exterior to sweat-absorbing sponge segments, McConville does not teach or suggest an arrangement in which elastic segments are smaller than and attached to the inelastic segment on an exterior side of the inelastic segment. Even a reversal of the arrangement as proposed by the Examiner does not necessarily yield an elastic segment that is smaller than the portion of the inelastic segment it spans when the elastic segment is not stretched. The Examiner has not provided any specific showing that if McConville were modified to include a non-elastic band sized to fit around the wearer’s head that such an arrangement would also include elastic segments on an exterior portion of the non-elastic band.

The Examiner has stated as a rationale for the modification of McConville that “such a change would work in the same manner and in order to provide a lower amount of elasticity due to the smaller amount of elastic in the headband.” However, the Examiner has not provided any specific teaching or suggestion in McConville or elsewhere that providing a “lower amount of elasticity” is intended or desired. Indeed, McConville specifically notes that the elastic headband “can be stretched to fit a variety of users” and that the elastic band “allows the sweat band to be firmly placed on the user’s forehead.” McConville, col. 2, lines 47-56. Such teachings clearly indicate that the Examiner’s proposed reversal of the arrangement of McConville (i.e., the proposed modification of the segment sized to fit around the wearer’s head being made of an inelastic material, not an elastic material) for the purpose of lowering elasticity would render McConville unsuitable for its intended purpose of holding the band in firmly in place and allowing the band to be stretched to fit many users.

Further, the Examiner has not provided any objective rationale for modifying McConville to include elastic segments that are smaller than and attached to the inelastic segment on an exterior side of the inelastic segment. As provided in the present

application, such segments may provide visual indications of proper tension. *See* Specification, paragraph [0022]. However, in McConville no teaching or suggestion of using the slackness of a smaller elastic segment attached to an exterior of a headband is provided. Accordingly, there is no objective reason, other than impermissible hindsight reconstruction on the part of the Examiner, to modify McConville to include such segment on an exterior portion of a headband.

For at least the reasons outline above, the Applicants respectfully request withdrawal of the rejection of claims 1, 4-7, 19, and 22-28 under 35 U.S.C. § 103(a).

Rejection of claim 2, 3, 20, and 21 as being unpatentable over McConville, in view of Westbrook and further in view of the German patent document

Dependent claims 2, 3, 20, and 21 incorporate the recitations of independent claims 1 and 19, respectively. As noted above, the McConville and Westbrook references, either alone or in combination, do not appear to disclose all of the features of independent claims 1 and 19. The combination of McConville and Westbrook with the German patent document does not appear to overcome the deficiencies of McConville and Westbrook. Therefore, Applicants respectfully assert that the rejection of dependent claims 2, 3, 20, and 21 under 35 U.S.C. §103(a) should be withdrawn.

Conclusion

In view of the remarks set forth above, Applicants respectfully request reconsideration of the Examiner's rejections and allowance of all pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

General Authorization for Extensions of Time

In accordance with 37 C.F.R. § 1.136, Applicants hereby provide a general authorization to treat this and any future reply requiring an extension of time as incorporating a request therefor. Furthermore, Applicants authorize the Commissioner to charge the appropriate fee for any extension of time to Deposit Account No. 06-1315; Order No. TYHC:0127/FLE/BAK (P0402S-01).

Respectfully submitted,

Date: June 23, 2009

/Jila Bakker/

Jila Bakker
Reg. No. 53,962
(281) 970-4545

COVIDIEN
IP Counsel-Respiratory & Monitoring Solutions
60 Middletown Avenue
North Haven, CT 06473